The FDA Provides Interim Results of Duodenoscope Reprocessing Studies Conducted in Real-World Settings: FDA Safety Communication

Date Issued: December 10, 2018

Audience:

- Patients considering Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures.
- Users and reprocessors of duodenoscopes including:
    - Gastroenterologists
    - Gastrointestinal surgeons
    - Endoscopy nurses
    - Staff working in endoscopy reprocessing units in health care facilities
    - Infection control practitioners
    - Personnel conducting endoscope culturing (e.g., clinical diagnostic and laboratory staff)
    - Facility risk managers
    - Patients considering Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures

Medical Specialties: Gastroenterology, Infection Control

Device: All Endoscopic Retrograde Cholangiopancreatography (ERCP) endoscopes (side-viewing duodenoscopes)

Purpose

The FDA is providing interim results from the ongoing mandated postmarket surveillance studies ("522 study") (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) to inform patients, hospitals and health care facilities of higher-than-expected contamination rates with duodenoscopes after reprocessing. Facilities and staff that reprocess duodenoscopes are reminded of the importance of manual cleaning prior to disinfection or sterilization and proper servicing of duodenoscopes.

Summary of Problem and Scope

Duodenoscopes (/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes) are complex instruments that contain many small working parts. If reprocessing instructions are not followed in every step of the process, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient transmission of infection.

On October 5, 2015, the FDA ordered all three manufacturers (Fujifilm Medical Systems USA, Inc, Olympus Medical Systems Corporation, Pentax of America), who make duodenoscopes sold in the U.S. to conduct postmarket surveillance studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) so the FDA can better understand how duodenoscopes are reprocessed in real-world settings.

As of November 2018, the initial Human Factors Study testing has been completed and at least 10% of the samples have been collected for the Sampling and Culturing Study.

The FDA is providing interim results from the ongoing postmarket surveillance studies to inform hospitals and health care facilities that use duodenoscopes of the continued need to carefully clean and properly maintain these important and life-saving medical devices.

Human Factors Study Question: Are the user materials included in your duodenoscope labeling and instructions for use sufficient to ensure user adherence to your reprocessing instructions? (Note: User materials include user manuals, brochures, and quick reference guides from the manufacturer that are provided to the reprocessing staff.)

- Human factors study results indicate that reprocessing instructions in current user manuals are difficult for reprocessing staff to comprehend and follow. For example, some reprocessing staff missed one or more steps in the process and needed additional training to complete the process properly. The study revealed that the descriptions of some of the processing steps in the user manuals were unclear. As a result, the FDA is working with the duodenoscope manufacturers to revise and clarify the user materials to improve comprehension and adherence to reprocessing instructions.

Sampling and Culturing Study Questions: After use of your labeled reprocessing instructions, what percentage of clinically used duodenoscopes remain contaminated with viable microorganisms? For devices that remain contaminated after use of your labeled reprocessing instructions, what factors contribute to microbial contamination and what steps are necessary to adequately decontaminate the device?

At least 10% of the samples have been collected for the Sampling and Culturing studies. The studies were designed assuming less than a 0.4% contamination rate.

- Interim results from these studies indicate higher-than-expected contamination rates after reprocessing, with up to 3% of properly collected samples testing positive for enough low concern organisms to indicate a reprocessing failure and up to 3% of properly collected samples testing positive for high concern organisms. High concern organisms are defined as organisms that are more often associated with disease, such as *E. coli*, and *Pseudomonas aeruginosa*. Root cause analyses are currently underway to better understand these culturing results. Some factors that may contribute to device contamination after reprocessing include device damage and errors in reprocessing. These results are preliminary; final results are expected in 2019.

Interim results for each duodenoscope manufacturer are available on the respective FDA 522 Postmarket Surveillance Studies webpage (Fujifilm (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=353&c_id=3725), Pentax (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=355&c_id=3727), and Olympus (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3726)).

Recommendations for Facilities and Staff that Reprocess Duodenoscopes

The FDA recommends facilities and staff strictly adhere to the manufacturer's reprocessing and maintenance instructions and follow these best practices:

- Meticulously clean the elevator mechanism and the recesses surrounding the elevator mechanism by hand, even when using an automated endoscope reprocessors (AERs) (/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation). Raise

and lower the elevator throughout the manual cleaning process to allow brushing and flushing of both sides. After cleaning, carefully inspect the elevator recess and repeat cleaning if any soil or debris is visible.

- Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.
- Follow the duodenoscope manufacturer's recommendations for inspection, leak testing, and maintenance of the duodenoscope.
    - Prior to each use, closely inspect and remove from service for assessment, and repair or replace any duodenoscope that shows visible signs of damage, as recommended in the duodenoscope instruction manuals. Examples of damage may include: loose parts, protrusions or abnormal bulging from the endoscope, kinks or bends in tubing, cracks and gaps in the adhesive that seals the device's distal cap or other signs of wear or damage.
    - During each reprocessing cycle, conduct leak testing and remove from service for assessment, and repair and replace any duodenoscope that shows signs of leakage. Follow the duodenoscope manufacturer's leak testing instructions for angulating the bending section and elevator during leak testing.
    - As recommended in the duodenoscope instruction manuals, return the duodenoscope to the duodenoscope manufacturer for inspection, servicing, and maintenance of the device at least once per year.
- Be aware that FDA has previously issued a Safety Communication (http://wayback.archive-it.org/7993/20170722150658/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and provided a detailed list of supplemental duodenoscope reprocessing measures that can be implemented to reduce the risk of infection transmission, such as: microbiological culturing, sterilization, use of a liquid chemical sterilant processing system and repeat high-level disinfection. Hospitals and health care facilities that utilize duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices.

Information for Patients

You may be aware of incidents where inadequately reprocessed reusable medical devices were used on patients. The risk of infection from inadequate reprocessing is relatively low, and the FDA recommends that you do not cancel or delay any planned procedure without first discussing with your health care professional.

Before having any medical procedure it's a good idea to learn more about the procedure and steps the health care facility takes to keep patients safe.

Your health care provider is one resource for information about your medical care. Many organizations, including The American Academy of Family Physicians (http://familydoctor.org/online/famdocen/home/pat-advocacy/healthcare/837.html) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) provide tips for talking to your doctor.

Recent FDA Activities:

The FDA is actively engaged with many of these stakeholder groups to better understand the causes and risk factors for transmission of infectious agents and develop solutions to minimize patient exposure.

On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), and American Society for Microbiology (ASM), together with other endoscope culturing experts, released voluntary standardized protocols for duodenoscope surveillance sampling and culturing (/media/111081/download). These protocols are an update to the Interim Duodenoscope Surveillance Protocol released by CDC in March 2015, and address the concerns regarding validation of duodenoscope culturing protocols raised in ASM's April 2015 Policy Statement on Culturing of Duodenoscopes.

On March 9, 2018, the FDA issued Warning Letters (/news-events/press-announcements/fda-warns-duodenoscope-manufacturers-about-failure-comply-required-postmarket-surveillance-studies) to all three manufacturers who make duodenoscopes sold in the U.S. for failure to provide sufficient data to address the postmarket surveillance studies requirements under Section 522 of the Federal Food, Drug, and Cosmetic Act. All three manufacturers responded to the warning letters and submitted plans that outline how study milestones will be achieved including enrolling new sites and collecting samples.

The FDA continues to:

- Carefully track cases of infection with multi-drug resistant bacteria and the use of duodenoscopes through medical device adverse event reports (/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems) submitted to the FDA, literature and stakeholders feedback.
- Work with health care facilities and reprocessing personnel to understand their experiences implementing reprocessing protocols.
- Work with the companies to modify the reprocessing instructions to enhance the safety margin of methods used to clean, disinfect and sterilize duodenoscopes.
- Encourage the development of new technology and design features, such as disposable components, to enhance patient safety, especially when a life-saving procedure such as identifying cancer by ECRP is necessary.

The FDA will continue to provide additional information to the public as new information becomes available.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products. If you suspect or experience a problem with a laboratory test, we encourage you to file a voluntary report through MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.